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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/385,834 08/30/99 WRIGHT

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EXAMINER

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DAZI, S

ART UNIT	PAPER NUMBER
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1616

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DATE MAILED:

07/03/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
09/385,834

Applicant(s)

Jeffery L.C. Wright

Examiner

Sabiha N. Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jun 7, 2001

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1, 5-11, and 30-39 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1, 5-11, and 30-39 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

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**Office Action on Merits**

**Status of the application**

Claims 1, 5-11, 30-39 are pending.

Claims 1, 5-11, 30-39 are rejected.

Elected group is examined.

New claims 32-39 are added.

No claim is allowed.

Applicant's response filed in paper no. 6/7/01 and request for continued examination is hereby acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5-11 and 30-39 stand rejected under 35 U.S.C. 112, first paragraph, for the same reasons set forth in our previous action, for containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are no examples in the specification showing any data for lowering cholesterol or triglycerides as has been instantly

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claimed. One example for the synthesis of the ester was found in the specification. Applicant's arguments regarding the synthesis has been noted by the Examiner. Examiner respectfully disagree with the arguments because there is no data for what has been claimed. No example for how the invention will work is disclosed. Applicants must show the support in terms of data in vitro or vivo to support the claimed invention.

One skilled in the art would have to do undue experimentation to practice the instant invention. There is no support for what has been claimed. Instantly claimed invention is drawn to nutrition supplement comprising a sterol ester of an omega fatty acid for lowering cholesterol and triglycerides levels in the blood stream of a subject. No examples or data is provided.

***Claim Rejections - 35 USC § 103***

1. Claims 1, 5-11, 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miettinen et al. (EPA 594,612, WO9219640) in view of Alexander et al. (The New England Journal of Medicine, Vol. 318, No. 9, pages 549-547). See the entire documents.

Instant claims are drawn to composition, preparation and method of use comprising a at least one phytostenol ester of a

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conjugated fatty acid having from for lowering serum cholesterol.

Miettinen et al. teaches fatty acid composition of  $\beta$ -sitostanol ester mixtures containing large amount of monoenes and polyenes, whereby the efficacy in lowering the cholesterol levels in serum are enhanced. See the entire document especially lines 40-45, and lines 56-58 on page 4. See also examples 1-3.

Instant claims differ from the reference in claiming at least one phytostenol ester of a conjugate acid for reducing the serum cholesterol whereas Miettinen et al. teaches that a mixture of  $\beta$ -sitostanol ester with polyenes or monoenes for lowering the cholesterol level.

Alexander et al. alleviates the deficiency of Miettinen et al. because it teaches the n-3 fatty acids for lowering the low-density lipoprotein (LDL) cholesterol. See last para of col. 2 on page 549. The reference also teach dietary fish and fish oil supplements on plasma lipid levels and reduction of triglyceride levels. See Fig. 2 for the elected species eicosapentaenoic acid.

The two references are combined because they are from the same field.

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One skilled in the art would find ample motivation from the prior art supra to combine the teachings of Alexander et al. and Miettinen et al. by using sterol ester and omega-3 fatty acid of known properties. In this case sterol ester and omega-3 fatty acid or ester are well known dietary supplements for lowering the cholesterol and triglyceride levels.

It would have been obvious to one skilled in the art to be motivated to prepare an sterol ester with unsaturated fatty acid to reduce the serum cholesterol because prior teaches that unsaturated fatty acid especially omega-3 fatty acid posses excellent property of reducing the serum cholesterol. Instant composition and methods would have been obvious to one skilled in the art at the time of invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious

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over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2. Claims 1, 5-11, 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell, David (US Patent 4,588,717). See the entire documents. Mitchell teaches phytosterol composition which embraces Applicant's claimed invention. See lines 20-32, col. 5; lines 30-68, col. 6; col. 7; col. 8, particularly lines 32-37; cols 9 and 10 and all the examples where composition of esters of phytosterol prepared by unsaturated fatty acids are described. All phytosterol are included (see lines 23-30, col. 5). Reaction between an sterol and any given fatty acid is essentially the same (lines 33-37, col. 8). Equation 1 in col. 8 is shown as alpha sitosterol as a sterol and linoleic acid as a fatty acid to form sitosterol fatty acid ester. Alpha sitosterol is the isomer of beta-sitosterol which differs in the position of double in the ring.

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Instant claims differ from the reference in claiming specifically sterol esters of omega-3 fatty acid esters composition whereas prior teaches sterol esters of any unsaturated fatty acid which includes instantly claimed invention.

One having ordinary skilled in the art would have been motivated to prepare the instant composition of sterol esters of omega-3-fatty acids because prior art teaches such composition. Instant invention is the selection of prior art invention. One would find ample motivation from the prior art to prepare the instant invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

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In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

#### **Conclusion**

Examiner would like to emphasize that elected invention instant application are drawn to composition claims and not to method of use claims. It would have been obvious to prepare additional beneficial compositions as disclosed by the prior art for the reason cited above.

Even if in case when prior art does not teach the same use, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPO 324; *Ex parte Douros*, 163 USPO 667; and *In re Craige*, 89 USPO 393.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious

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over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293. All the sterol fatty esters as instantly claimed are taught by the prior art of record. Upon carefully reviewing the references and instant invention, claims 1, 5-11, 30-39 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Miettinen et al. (EPA 594,612) in view of Alexander et al. (The New England Journal of Medicine, Vol. 318, No. 9, pages 549-547).

***Telephone Inquiry Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

6/28/01

*S. Qazi*  
SABIHA QAZI, PH.D  
PRIMARY EXAMINER